

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1317-P]

RIN 0938-A011

**Medicare Program; Revisions to the Payment Policies of
Ambulance Services under the Fee Schedule for Ambulance
Services**

AGENCY: Centers for Medicare & Medicaid Services (CMS),
HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to set forth changes to the fee schedule for payment of ambulance services by adopting revised geographic designations for urban and rural areas as set forth in Office of Management and Budget's (OMB) Core-Based Statistical Areas (CBSAs) standard. We propose to remove the definition of Goldsmith modification and reference the most recent version of Goldsmith modification in the definition of rural area. In addition, we propose to add the definition of urban area as defined by OMB and revise our definitions of emergency response, rural area, and specialty care transport (SCT).

We also propose to discontinue the annual review of the conversion factor (CF) and of air ambulance rates. We would continue to monitor payment and billing data on an ongoing

basis and make adjustments to the CF and to air ambulance rates as appropriate to reflect any significant changes in these data.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1317-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. Electronically. You may submit electronic comments on specific issues in this proposed regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:
Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1317-P,

P.O. Box 8017,

Baltimore, MD 21244-8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1317-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7197 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building,
200 Independence Avenue, SW.,
Washington, DC 20201; or
7500 Security Boulevard,
Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government

identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Anne Tayloe, (410)786-4546.

SUPPLEMENTARY INFORMATION:

Submitting Public Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1317-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all comments received before the close of the comment period on its public Web site as soon as

possible after they have been received. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Under the ambulance fee schedule, the Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the following levels of service:

- For Ground--
 - ++ Basic Life Support (BLS)
 - ++ Advanced Life Support, Level 1 (ALS1)
 - ++ Advanced Life Support, Level 2 (ALS2)
 - ++ Specialty Care Transport (SCT)
 - ++ Paramedic ALS Intercept (PI)
- For Air--
 - ++ Fixed Wing Air Ambulance (FW)
 - ++ Rotary Wing Air Ambulance (RW)

A. History of Medicare Ambulance Services

1. Statutory Coverage of Ambulance Services

Under sections 1834(1) and 1861(s)(7) of the Social Security Act (the Act), Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that--

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and

- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set

forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at §410.12 and to specific conditions and limitations included at §410.40. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

The national fee schedule for ambulance services is being phased in over a 5-year transition period beginning April 1, 2002. (See §414.615). In accordance with section 414 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173), we added new §414.617 which specifies that for ambulance services furnished during the period July 1, 2004 through December 31, 2009, the ground ambulance base rate is subject to a floor amount, which is determined by establishing nine fee schedules based on each of the nine census divisions, and using the same methodology as was used to establish the national fee schedule. If the regional fee schedule methodology for a given census division results in an amount that is lower than or equal to the national ground base rate, then it is not used, and the national fee schedule amount applies for all providers and suppliers in the census division. If the regional fee schedule methodology for a

given census division results in an amount that is greater than the national ground base rate, then the fee schedule portion of the base rate for that census division is equal to a blend of the national rate and the regional rate. For CY 2006, this blend would be 40 percent regional ground base rate and 60 percent national ground base rate. As of January 1, 2006, the total payment amount for air ambulance providers and suppliers will be based on 100 percent of the national ambulance fee schedule, while the total payment amount for ground ambulance providers and suppliers will be based on either 100 percent of the national ambulance fee schedule or 60 percent of the national ambulance fee schedule and 40 percent of the regional ambulance fee schedule.

II. Provisions of the Proposed Rule

In this proposed rule, we would set forth changes to the fee schedule for payment of ambulance services by adopting revised geographic designations for urban and rural areas as set forth in OMB's Core-Based Statistical Areas (CBSAs) standard. We propose to remove the definition of Goldsmith modification and reference the most recent version of Goldsmith modification in the definition of rural area. In addition, we propose to add the definition of urban area already defined by OMB.

We are also proposing to revise the definition of

specialty care transport (SCT) to clarify that a hospital is the only appropriate origin and destination point for this level of care.

In addition, we are proposing to discontinue our annual review of the CF and of air ambulance rates because we have not identified any significant differences from those assumptions in the 4 years since the implementation of the fee schedule. We would continue to monitor payment and billing data on an ongoing basis and make adjustments to the CF and to air ambulance rates as appropriate to reflect any significant changes in these data.

Finally, we are proposing to revise our current definition of emergency response to specify the conditions that warrant payment for immediate response.

A. Adoption of New Geographic Standards for the Ambulance Fee Schedule

Historically, the Medicare ambulance fee schedule has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to take into account appropriate urban and rural differences. While this promotes consistency across the Medicare program, it also provides a consistent and objective national definition for payment purposes and utilizes geographic area designations that more realistically reflect rural and urban populations,

resulting in more accurate payments for ambulance services.

As a result, we are proposing to adopt OMB's CBSA-based geographic area designations to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We also propose to update the Goldsmith standard, consistent with the provisions of section 1834(l), to more accurately determine rural census tracts within metropolitan areas.

These changes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because ambulance payments are based on the point of pick-up for the transport, and the point of pick-up for urban and rural transport is paid differently. Of particular significance to the ambulance fee schedule, the changes would affect whether or not certain areas are eligible for certain rural bonus payments under the ambulance fee schedule. For example, the changes would affect whether or not certain areas are recognized as what we refer to as "Super Rural Bonus" areas established by section 414(c) of the MMA and set forth in §1834(l)(12) of the Act. That section specifies that, for services furnished during the period July 1, 2004 through December 31, 2009, the payment amount for the ground ambulance base rate is increased by a "percent increase" (Super Rural Bonus) where the ambulance

transport originates in a rural area (which includes Goldsmith areas) that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density.

1. Core-Based Statistical Areas (CBSAs)- Revised Office of Management and Budget (OMB) Metropolitan Area Definitions [If you choose to comment on issues in this section, please include the caption "CBSAs-REVISED OMB METROPOLITAN AREA DEFINITIONS" at the beginning of your comments.]

In the February 27, 2002 final rule (67 FR 9100), we stated that we could not easily adopt and implement, within the timeframe necessary to implement the fee schedule, a methodology for recognizing geographic population density disparities other than MSA/nonMSA. We also stated that we would consider alternative methodologies that may more appropriately address payment to isolated, low-volume rural ambulance providers and suppliers at a later date. The application of any rural adjustment is determined by the geographic location of the beneficiary at the time he or she is placed on board the ambulance. We are now proposing to adopt OMB's revised geographic area designations for urban and rural areas to address payment to those isolated, low-volume rural providers and suppliers.

Prior to the 2000 decennial census, geographic areas were consistently defined by OMB as Metropolitan Statistical

Areas (MSAs) with an MSA being defined as an urban area and anything outside an MSA being defined as a rural area. In addition, for purposes of ambulance policy, we recognized the 1990 update of Goldsmith areas (generally, rural census tracts within counties that covered large tracts of land with one predominant urban area only) as rural areas (65 FR 55077 through 55100). In the fall of 1998, OMB chartered the Metropolitan Area Standards Review Committee to examine the Metropolitan Area (MA) standards and develop recommendations for possible changes to those standards. Three notices related to the review of the standards were published on the following dates in the **Federal Register**, providing an opportunity for public comment on the recommendations of the Committee: December 21, 1998 (63 FR 70525 through 70561); October 20, 1999 (64 FR 56627 through 56644); and August 22, 2000 (65 FR 51059 through 51077).

In the December 27, 2000, **Federal Register** (65 FR 82227 through 82238), OMB announced its new standards. In that notice, OMB defines a CBSA, beginning in 2003, as "a geographic entity associated with at least one core of 10,000 or more population, plus adjacent territory that has a high degree of social and economic integration with the core as measured by commuting ties." CBSAs are conceptually areas that contain a recognized population nucleus and adjacent communities that have a high degree of

integration with that nucleus. The purpose of the new OMB standards is to provide nationally consistent definitions for collecting, tabulating, and publishing Federal statistics for a set of geographic areas.

The OMB standards designate and define two categories of CBSAs--Metropolitan Statistical Areas (MSAs) and Micropolitan Statistical Areas. (65 FR 82227 through 82238) According to OMB, MSAs are based on urbanized areas of 50,000 or more population and Micropolitan Statistical Areas (referred to in this discussion as Micropolitan Areas) are based on urban clusters of at least 10,000 population but less than 50,000 population. Counties that do not fall within CBSAs are deemed "Outside CBSAs."

Under the ambulance fee schedule, MSAs would continue to be recognized as urban areas and all other areas outside MSAs (including Micropolitan areas, areas "outside CBSAs", and areas that meet the updated definition of the Goldsmith Modification) would be recognized as rural areas. As noted previously, these designations are important because under the ambulance fee schedule, Medicare transports are designated either urban or rural based on the pick-up point of the transport.

The new OMB definitions recognize 49 new MSAs and 565 new Micropolitan Areas, and extensively revise the composition of many of the existing MSAs. There are 1,090

counties in MSAs under the new definitions (previously, there were 848 counties in MSAs). Of these 1,090 counties, 737 are in the same MSA as they were prior to the changes, 65 are in a different MSA, and 288 were not previously designated to any MSA.

There are 674 counties in Micropolitan Areas. Of these, 41 were previously in an MSA, while 633 were not previously designated to an MSA. There are five counties that previously were designated to an MSA, but are no longer designated to either an MSA or a new Micropolitan Area (Carter County, Kentucky; St. James Parish, Louisiana; Kane County, Utah; Culpepper County, Virginia; and King George County, Virginia).

The adoption of CBSA-based geographic area designations would mean that ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be outside of MSAs (but are currently within MSA areas) may experience increases in payment, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be within MSA areas (but are currently outside of MSAs) may experience decreases in payment.

The use of updated geographical areas would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 1990 and 2000. In general, it is expected that

ambulance providers and suppliers in 22 States may experience payment increases and ambulance providers and suppliers in 40 States may experience payment decreases as a result of population shifts recognized by OMB's CBSA-based geographic area designations.

We believe that updating the MSA definition to conform with OMB's CBSA-based geographic area designations, coupled with updating the Goldsmith Modification (that is, using the current Rural Urban Commuting Areas version, as discussed in Section 2 of this proposed rule), would more accurately reflect the contemporary urban and rural nature of areas across the country for ambulance payment purposes and cause ambulance fee schedule payments to become more accurate.

As of October 1, 2004, the IPPS adopted OMB's revised metropolitan area definitions to identify "urban areas" for payment purposes. Under the IPPS, MSAs are considered urban areas and Micropolitan Areas and areas "Outside CBSAs" are considered rural areas (§412.64(b)). We are proposing to adopt similar CBSA-based designations of "urban area" and "rural area" under the ambulance fee schedule for the reasons discussed. Therefore, we propose to revise §414.605 to include a definition of urban area and to reflect OMB's revised CBSA-based geographic area designations in our definition of rural area.

2. Updated Goldsmith Modification - Rural Urban Commuting Areas (RUCAs)

[If you choose to comment on issues in this section, please include the caption "RUCAs" at the beginning of your comments.]

The Goldsmith Modification evolved from an outreach grant program sponsored by the Office of Rural Health Policy of the Health Resources and Services Administration (HRSA). This program was created to establish an operational definition of rural populations lacking easy access to health services in Large Area Metropolitan Counties (LAMCs). Dr. Harold F. Goldsmith and his associates created a methodology for identifying rural census tracts located within a large metropolitan county of at least 1,225 square miles. Using a combination of data on population density and commuting patterns, census tracts were identified as being so isolated by distance or physical features that they were more rural than urban in character. The original Goldsmith Modification was developed using data from the 1980 census. In order to more accurately reflect current demographic and geographic characteristics of the nation, HRSA's Office of Rural Health Policy, in partnership with the Department of Agriculture's Economic Research Service and the University of Washington, developed an update to the Goldsmith modification designated as Rural-Urban Commuting

Area Codes (RUCAs) (69 FR 47518 through 47519).

Rather than being limited to LAMCs, RUCAs use urbanization, population density, and daily commuting data to categorize every census tract in the country. RUCAs are used to identify rural census tracts in all metropolitan counties. Section 1834(l) of the Act requires that we include the most recent modification of the Goldsmith Modification to determine rural census tracts within MSAs. Therefore, we propose to remove the definition of "Goldsmith modification" at §414.605 and incorporate a reference to the most current version of the Goldsmith modification in the definition of "rural area."

B. Specialty Care Transport (SCT)

[If you choose to comment on issues in this section, please include the caption "SPECIALTY CARE TRANSPORT" at the beginning of your comments.]

On February 27, 2002, we published a final rule with comment period in the **Federal Register** (67 FR 9100) entitled "Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services" that implemented the ambulance fee schedule. In that final rule, we defined SCT in §414.605 as the "interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary

supplies and services, at a level of service beyond the scope of the EMT [(Emergency Medical Technician)]-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training."

Additionally, ambulance vehicle staff are to be certified as emergency medical technicians and legally authorized to operate all lifesaving and life-sustaining equipment that are on board the vehicle. (§410.41(b)(1)) Typically, a SCT level of care occurs when the patient, who is already receiving a high level of care in the transferring acute care hospital, requires a level of care that the transferring hospital is not able to provide.

We implemented the SCT level of payment for hospital-to-hospital ground ambulance transports upon implementation of the ambulance fee schedule on April 1, 2002 and we defined SCT at §414.605. The definition of SCT in §414.605 refers to "interfacility transportation." We based our payment for SCT-level ground ambulance transports on hospital-to-hospital ambulance transportation data. As we stated in the preamble to the February 27, 2002 final rule (67 FR 9100), the SCT level of

care includes the situation where a beneficiary is taken by ground ambulance from the hospital to an air ambulance and then from the air ambulance to the final destination hospital. Also, we stated in the preamble for both the September 12, 2000 (65 FR 55077) proposed rule and the February 27, 2002 (67 FR 9108) final rule, that SCT is a level of interhospital service. However, transfer to or from a type of facility other than a hospital (for example, skilled nursing facility or nursing home) is not SCT.

Subsequent to the implementation of the ambulance fee schedule, we clarified our definition of SCT as hospital-to-hospital transport in a Program Memorandum to Medicare contractors, which was issued on September 27, 2002. (Program Memorandum Intermediaries/Carriers, Transmittal AB-02-130 - Change Request 2295, September 27, 2002) That document and subsequent questions and answers related to the definition of SCT were made available to the public on the CMS Medicare ambulance policy Web site.

In addition, we clarified our definition of SCT in the Medicare Benefit Policy Manual, Chapter 10-Ambulance Services, in which we stated that SCT is regarded as a highly-skilled level of care of a critically injured or ill patient during transfer from one hospital to another. We have also clarified our policy in Ambulance Open Door Forums, conference calls, and oral and paper communication

written in response to questions posed by individuals and groups representing the ambulance industry.

Despite our previous attempts to clarify the scope of SCT transport we nonetheless continue to receive questions. For this reason, we are proposing to revise the definition of "specialty care transport" at §414.605 to read "hospital-to-hospital" transport as opposed to "interfacility" transportation. We believe this change would make it absolutely clear that a hospital is the only appropriate origin and destination point for the SCT level of care. Since this clarification would only conform the regulation text to our current policy on this issue, there would be no change in policy; there would be no additional cost to the Medicare program, its contractors or ambulance providers and suppliers.

C. Recalibration of the Ambulance Fee Schedule Conversion Factor

[If you choose to comment on issues in this section, please include the caption "RECALIBRATION OF THE AMBULANCE FEE SCHEDULE" at the beginning of your comments.]

In the February 27, 2002 final rule with comment period, (67 FR 9102 and 9103), we indicated that we would adjust the conversion factor(CF) if actual experience under the fee schedule was significantly different from the assumptions used to determine the initial CF and air

ambulance rates. We said specifically that we would monitor payment data and evaluate whether the assumptions used were accurate.

We have continued to review our assumptions annually to determine whether or not a conversion factor adjustment is warranted. We examined the effects of the relative volumes of the different levels of ambulance services (service mix) and the extent of low billing charges to determine whether we should adjust the CF to reflect actual practices. In the 4 years since the implementation of the ambulance fee schedule, no significant differences from our original assumptions have emerged. We have observed only insignificant differences, and, to date, no adjustments in any one year have been warranted. It is for this reason, we believe it is appropriate to discontinue our annual review of the original conversion factor assumptions. We also believe that the formal annual review of air ambulance rates should be discontinued as we propose to monitor all ambulance rates and make adjustments on an "as-needed" basis. We would continue to monitor payment and billing data on an ongoing basis and, if actual practices under the fee schedule differ significantly from any of our assumptions, we would adjust the CF and air ambulance rate appropriately. The ambulance industry has available multiple venues for notifying CMS of potential issues.

These are the ambulance fee schedule open door forums, and telephone calls to CMS-designated personnel. As an additional safeguard, CMS generally conducts a review of ambulance data each year in preparation for issuing the Ambulance Inflation Factor (AIF). Therefore, we propose to revise the annual review requirement at §414.610(g) to indicate that we will adjust the CF and air ambulance rates when appropriate to take into account actual practices under the fee schedule when these differ significantly from assumptions we use to calculate the CF and air ambulance rates.

D. Hospital-to-Hospital Ambulance Service - Emergency Response

[If you choose to comment on issues in this section, please include the caption "EMERGENCY RESPONSE" at the beginning of your comments.]

In §414.605, we define "emergency response" of an ambulance service to mean "responding immediately at the BLS[(Basic Life Support)] or ALS1[(Advanced Life Support Level 1)] level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance entity begins as quickly as possible to take the steps necessary to respond to the call." In our February 27, 2002 final rule (67 FR 9100) defining "emergency response", we stated that the additional

payment for emergency response is for the additional overhead cost of maintaining the resources required to respond immediately to a call and not for the cost of furnishing a certain level of service to the beneficiary.

The current "emergency response" definition has created confusion for those transports that originate at a hospital emergency department and the ambulance is transporting the beneficiary to an emergency department at another hospital for either admittance or treatment. For example, in most of these cases, the beneficiary must be stabilized prior to the transport. Therefore, the need to maintain a state of readiness to respond immediately to an urgent call, warranting a higher emergency response payment, does not appear to be applicable to these situations.

Another example occurs when the ambulance is owned by the originating hospital. We stated in a Program Memorandum to the Medicare contractors (Transmittal AB-02-130, Change Request 2295, September 27, 2002) that upon receipt of a call for ambulance services, the dispatcher makes the determination of whether the call constitutes an "emergency response". When the ambulance service is already readily available at the originating hospital, an emergency call may not be necessary, much less through a dispatcher for a 911 service.

While we recognize that there may be instances when an

emergency response payment is warranted for a transport between two hospital emergency departments, we believe that payment based on readiness to respond immediately is not justified 100 percent of the time. For this reason, we believe our current definition of "emergency response" needs to be revised to reflect only circumstances where payment for immediate response is truly warranted. Therefore, we are proposing to revise the definition of "emergency response" as follows:

"Emergency response" means that an ambulance entity--

- Maintains readiness to respond to urgent calls at the BLS or ALS1 level of service; and
- Responds immediately at the BLS or ALS1 level of service to 911 calls, the equivalent in areas without a 911 call system or radio calls within a hospital system when the ambulance entity is owned and operated by the hospital.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We

will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact

[If you choose to comment on issues in this section, please include the caption "REGULATORY IMPACT" at the beginning of your comments.]

A. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Using CY 2004 data, we estimate that any urban

to rural population shifts reflected in the new proposed geographic designations could potentially result in an initial decrease in Medicare payments for all ambulance providers and suppliers of approximately \$4.6 million. However, this estimate assumes that the same number of ambulance trips would originate from the same pick-up points as were reported in CY 2004, an unlikely scenario where urban and rural populations are shifting. We expect the initial change in geographic designations to have little, if any, overall effect on ambulance payments (See Section B, Anticipated Effects). This proposed rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to 29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a

significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds and is located outside of a Metropolitan Statistical Area or in a rural census tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals since small rural hospitals generally do not own and operate ambulance services.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule

(and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

As noted in Section A, Overall Impact, we estimate, using CY 2004 data, that adopting CBSA-based urban and rural designations could potentially result in an initial decrease in Medicare payments for ambulance providers and suppliers of approximately \$4.6 million. However, we believe this is not likely to be the case. Rather, we believe that the overall effect of adopting the CBSA-based geographic definitions would result in a redistribution of payments from urban to rural areas in some States and from rural to urban areas in other States. As noted in Section A, in using CY 2004 data, we held the number and length of ambulance trips and the pick-up points constant in order to isolate the effect of the adoption of CBSA-based geographic areas. We believe this constant, for all practical purposes, is not likely to occur. We contend that with the use of updated geographical areas where rural areas are redesignated as urban areas, it will be more likely than not, that some level of population growth has occurred

resulting in more ambulance trips overall than had occurred in CY 2004, even though these trips are paid at a lower rate per trip (areas designated as rural generally receive a higher payment per trip than areas designated as urban).

In contrast, where urban areas are redesignated as rural, there will be fewer trips than was reported in CY 2004, but at higher rates. Thus, although ambulance suppliers and providers may bill fewer rural trips at the higher rate or more urban trips at the lower rate, we anticipate that the overall payments will remain the same. For these reasons, we estimate that this proposed rule will have no fiscal impact on the Medicare program because payments will, in effect, be redistributed.

C. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects 42 CFR Part 414

Administrative practice and procedure, Health facilities,
Health professions, Kidney diseases, Medicare, Reporting and
recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 414 - PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for Part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1834(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395m(1)).

Subpart H-Fee Schedule for Ambulance Services

2. Section 414.605 is amended by--

A. Removing the definition of Goldsmith modification.

B. Revising the definitions of emergency response, rural area, and specialty care transport (SCT).

C. Adding the definition of urban area in alphabetical order.

The revisions and addition read as follows:

§414.605 Definitions.

* * * * *

Emergency response means that an ambulance entity--

(1) Maintains readiness to respond to urgent calls at the BLS or ALS1 level of service; and

(2) Responds immediately at the BLS or ALS1 level of service to 911 calls, the equivalent in areas without a 911 call system or radio calls within a hospital system when the

ambulance entity is owned and operated by the hospital.

* * * * *

Rural area means an area located outside an urban area, or a rural census tract within a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith modification as determined by the Office of Rural Health Policy of the Health Resources and Services Administration.

Specialty care transport (SCT) means the hospital-to-hospital transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT-Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

Urban area means a Metropolitan Statistical Area, as defined by the Executive Office of Management and Budget.

* * * * *

3. Section 414.610, paragraph (g) is revised to read as follows:

§414.610 Basis of payment.

* * * * *

(g) Adjustments. The Secretary monitors payment and billing data on an ongoing basis and adjusts the CF and air ambulance rates as appropriate to reflect actual practices under the fee schedule which are significantly different from assumptions used to calculate the CF and air ambulance rates. These rates are not adjusted solely because of changes in the total number of ambulance transports.

(Catalog of Federal Domestic Assistance Program No. 93.778,
Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773,
Medicare--Hospital Insurance; and Program No. 93.774,
Medicare--Supplementary Medical Insurance Program)

Dated: _____

Mark B. McClellan,
Administrator,
Centers for Medicare & Medicaid
Services.

Approved: _____

Michael O. Leavitt,
Secretary.